REMARKS

Claims 1-23 were examined. Claims 1-23 have been amended. No claims have been cancelled. Claim 24 is newly presented. No new matter has been introduced.

Objections to the Specification

The examiner states that the abstract employs "means for" language and requests correction.

Rejections under 35 USC §102

Claims 1, 6 and 10 stand rejected under §102(b) as anticipated by Vincent (US 5,601,604).

Claims 1 and 11 stand rejected under §102(b) as anticipated by Bryant et al. (US 6,776,789).

Claims 1, 5, 15 and 17-20 stand rejected under §102(b) as anticipated by Ahmadi, et al. (US 4,602,911).

Claims 1-4 stand rejected under §102(b) as anticipated by Oritz, et al. (US 6,419,696).

Claims 1 and 11 stand rejected under §102(b) as anticipated by Gilbertson et al (US 5,064,431).

These grounds of rejection are respectively traversed.

Rejections under 35 USC §103

Claims 2-4 stand rejected under §103(a) as obvious Ahmadi in view of Berreklouw (US 6,790,229).

Claims 15, 16 and 21-23 stand rejected under §103(a) as obvious over Ahmadi et all (US 4,602,911).

Claims 13 and 14 stand rejected under §103(a) as obvious over Gilbertson in view of Carpentier et al. (US 6,217,610).

Claims 6, 8-9 and 12 stand rejected under §103(a) as obvious over Gilbertson as a matter of design choice.

These grounds of rejection are respectively traversed.

In one embodiment of the present invention, as set forth in claim 1, an implantable device is provided for controlling the internal circumference of an anatomic orifice or lumen. The implantable device has an adjustable member configured to adjust the dimensions of the implantable device. The implantable device is configured to be coupled to a faster that provides for fastening of said implantable device to tissue around the anatomic orifice or lumen. An adjustment tool actuates the adjustable member and provides for adjustment before, during or after the anatomic orifice or lumen resumes near normal to normal physiologic function. The adjustment member is positioned off plane relative to the implantable device to provide that the implantable device can be adjusted on a beating heart to cause leaflet coaptation. The adjustable member is positioned to enable attachment to and adjustment of the implantable device, and detachment from the implantable device and removal from the body under normal beating heart conditions.

Vincent discloses a gastric band for placement around the stomach. A band is provided that is coupled to a fill tube. The band is placed around a section of the stomach and then inflated. This reduces the size of the stomach at the location of the band. The gastric band of Vincent does not include and implantable device with an adjustable member that is an actual part of the implantable device. Instead, Vincent has a gastric band and a separate fill tube that is not part of the gastric band. The fill tube introduces a fluid to the band, creating an inflation and an eventual tightening of the stomach. Vincent does not have an adjustment tool as with the present invention. Instead, the adjustment made by Vincent inflates the gastric band. Because Vincent does not have an implantable device that includes an adjustable member, Vincent does not have a relationship of the adjustable member relative to the implantable device. In

claim 1 of the present invention, the adjustment member is positioned off plane relative to the implantable device to provide that the implantable device can be adjusted on a beating heart to cause leaflet coaptation. Vincent fails to suggest or teach such a relationship.

Ahmadi et al., discloses an adjustable ring. The ring has a coiled spring ribbon, illustrated in Figure 3(a), and a screw guide structure 40 mounted on the ring. A guide cylinder 44 of the screw guide structure 40 has a slot that extends in an axial direction through the entire guide cylinder 44. An adjusting tool 48 is coupled to the screw guide structure 40. The relationship between the adjusting tool 48 and the screw guide structure 40 is planar, and not non-planar as with the present invention. Because of the planar coupling relationship, the ring of Ahmadi et al. can not be adjusted on a beating heart to cause leaflet coaptation. Additionally, because of the planar coupling relationship of Ahmadi et al., there can be no adjustment of the ring with detachment of the adjusting tool 48 from the ring and removal from the body under normal beating heart conditions, as set forth in claim 1 of the present invention.

Bryant et al. discloses a cinch suture with first and second segments, a locking mechanism with rows of teeth. The cinch structure of Bryant et al. is used for closing surgical excision openings. The cinch suture of Bryant et al. does not have an implantable device for a heart valve that includes an adjustable member positioned in a non-planar relationship to the implantable device. The present invention, as set forth in claim 1, includes an implant device for a heart valve, while Bryant et al. is a cinch suture for closing a surgical excision opening. The cinch suture of Bryant et al. closes openings and can not be used to adjust an implantable device on a beating heart to cause leaflet coaptation. Additionally, the Bryant et al. cinch suture device can not be used to adjust an implantable device for the heart with adjustment, attachment detachment and removal of an adjustment tool, configured to be coupled to an adjustable member of an implantable device, from the body under normal beating heart conditions.

Ortiz et al. discloses the use of two support rings that are coupled to each other. The two rings form a coiled configuration and are used to trap at least a portion of a

heart valve to provide repair to the heart valve. Ortiz et al. does not have an implantable device. Instead, Ortiz et al. discloses that two support rings are used to provide support to a damaged heart valve. Ortiz et al. fails to teach or suggest an implantable device with an adjustment member configured to be coupled to an adjustment tool where there is a non-planar engagement between the adjustment member and the adjustment tool. Instead, the rings of Ortiz et al. provide support to the heart valve. With the present invention, as set forth in claim 1, an implantable device is provided. The implantable device of the present invention can be adjusted on a beating heart to cause leaflet coaptation. With the present invention, the implantable device has an adjustment member positioned to enable attachment to and adjustment of the implantable device, and detachment from the implantable device and removal from the body under normal beating heart conditions. Ortiz et al. fails to provide an implantable device with an adjustment member, with the positioning of the adjustment member be non-planar in order to achieve adjustment on a beating heart.

Gilbertson et al. discloses an annuloplasty ring for an orifice. The ring is made of a flexible fabric tube. Two drawstrings are included and are used to adjust the tube Unlike the present invention, Gilbertson et al. does not have an implantable device with an adjustable member positioned in a non-planar relationship relative to the implantable device. The ring of Gilbertson et al. does not address the need of adjusting an implantable device for a valve of a beating heart to cause leaflet coaptation.

Berreklouw discloses a cardiac prosthesis device that includes a valve prosthesis, and a tubular element. The tubular element has a bottom that is either bent or can be reversibly bent against a resilient force to provide for adjustment of the valve prosthesis. The combination of Berreklouw and Ahmadi et al. does not provide the present invention as set forth in claim 1. This combination does not change the fact that Ahmadi et al. has a screw guide structure 40 and an adjusting tool that have a non planar arrangement. The combination of these two references does not enable the Ahmadi device to adjust an implantable device on a beating heart to cause leaflet coaptation, nor does the combination of the two permit adjustment of the ring with

detachment of the adjusting tool 48 from the ring and removal from the body under normal beating heart conditions, as set forth in claim 1 of the present invention.

Claims 15, 16 and 21-23 have been rejected under §103(a) as obvious over Ahmadi et al. Claims 13 and 14 have been rejected under §103(a) as obvious over Gilbertson in view of Carpentier et al. (US 6,217,610) and Claims 6, 8-9 and 12 stand rejected under §103(a) as obvious over Gilbertson.

It is respectfully pointed out that none of these references, singularly or in combination provide for adjustment of an implantable device on a beating heart to cause leaflet coaptation, None of the references, singularly or in combination provide for adjustment of the implantable device with detachment of the adjusting tool from the implantable device and removal from the body under normal beating heart conditions, .

CONCLUSION

It is submitted that the present application is in form for examination, and such action is respectfully requested.

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 08-1641 (Docket No. 42749-0010).

Respectfully submitted,

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